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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/662,045	09/15/2000	Stefan Vilsmeier	SCHWP0129US	5003	
7	7590 01/16/2004		EXAMINER		
Don W. Bulson, Esq. Renner, Otto, Boisselle & Sklar, LLP			KIM, CH	KIM, CHONG R	
19th Floor			ART UNIT PAPER NUMB		
1621 Euclid Ave.			2623		
Cleveland, OH 44115			DATE MAILED: 01/16/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	n No.	Applicant(s)			
		09/662,045	5	VILSMEIER ET AL.			
	Office Action Summary	Examiner		Art Unit			
		Charles Kir	n	2623			
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1)⊠	Responsive to communication(s) filed on 2	03 November 20	<u>03</u> .				
2a) <u></u> □	This action is FINAL. 2b)⊠ This action is non-final.						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)⊠	⊠ Claim(s) <u>1-6 and 9-13</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)⊠	☑ Claim(s) <u>1-6 and 9-13</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8)□	8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers							
9)[9) The specification is objected to by the Examiner.						
10)⊠))⊠ The drawing(s) filed on <u>03 November 2003</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
_	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120							
* 5 13)	Acknowledgment is made of a claim for for All b) Some * c) None of: 1. Certified copies of the priority documed Certified copies of the priority documed Certified copies of the priority documed Certified copies of the certified copies of the application from the International Businesse the attached detailed Office action for a Acknowledgment is made of a claim for domince a specific reference was included in the Topic Certain	nents have been nents have been priority documer ureau (PCT Rule a list of the certifinestic priority under first sentence a provisional appressic priority undestic priority undestication and	received. received in Applications have been received 17.2(a)). ed copies not received der 35 U.S.C. § 119(a) of the specification or blication has been received der 35 U.S.C. §§ 120	on No ed in this National Stage d. e) (to a provisional application) in an Application Data Sheet. eived. and/or 121 since a specific			
Attachmer			r				
2) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948 mation Disclosure Statement(s) (PTO-1449) Paper No	3)		(PTO-413) Paper No(s) atent Application (PTO-152)			

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DETAILED ACTION

Response to Amendment and Arguments

1. Applicant's amendment filed on November 3, 2003 has been entered and made of record.

2. In view of applicant's amendment, the 112 second paragraph rejection is withdrawn.

In view of applicant's submitted formal drawings, the objection to the drawings are

withdrawn.

4. Applicant's arguments with respect to claim 1 have been considered but are moot in view

of the new ground(s) of rejection.

Claim Objections

5. Claims 1-13 are objected to because of typographical errors. It appears that the phrase

"one maker" in line 16 of claim 1 was intended to read "one marker". Appropriate correction is

required.

6. Claim 5 is objected to because the phrase "in which digital image signals are processed or

analog image signals, captured by said camera, are digitized and then processed" is

grammatically and typographically incorrect. It appears that the applicant intended the phrase to

read "in which digital image signals are processed, or analog image signals captured by said

camera are digitized and then processed". Appropriate correction is required.

The following quotation of 37 CFR § 1.75(d)(1) is the basis of objection:

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(d)(1) The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. (See § 1.58(a)).

7. Claims 4, 9, 11, 12 are objected to under 37 CFR § 1.75 (d)(1) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery.

Referring to claim 4, the phrase "said object" in line 4 lacks antecedent basis. The Examiner suggests removing the phrase from the claim. Appropriate correction is required.

Referring to claim 9, the phrase "said object" in lines 2 and 3 lack antecedent basis. The Examiner suggests changing the phrase to "said patient body part" for both instances.

Appropriate correction is required.

Referring to claim 11, the phrase "that shape" in line 2 lacks antecedent basis. The Examiner suggests changing the phrase to "a shape". Appropriate correction is required.

Referring to claim 12, the phrase "the user" in line 3 lacks antecedent basis. The Examiner suggests changing the phrase to "a user". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Referring to claim 1, the phrase "assigning a location and shape of the patient body part in the navigation system via a position of the at least one maker captured by the camera" in lines 15-17 is not sufficiently supported by the applicant's specification. More specifically, the applicant's specification is non-enabling in regards to how the shape of the patient body part is assigned in the navigation system via a position of the marker captured by the camera. It is unclear how the position of the marker can determine the shape of the patient body part.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 1-6, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cosman, U.S. Patent No. 6,006,126 ("Cosman") and the article entitled "Shape from Focus: An Effective Approach for Rough Surfaces" by Nayar et al. ("Nayar").

Referring to claim 1, Cosman discloses a method of detecting the shape of a patient body part to be treated, the method comprising the following steps:

a. applying at least one marker (508A) to the patient body part, the at least one marker being detectable by a navigation system (col. 10, lines 26-67 and figure 5)

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b. producing a camera image of the object (col. 10, lines 51-56 and figure 5)

- c. mapping a three-dimensional shape (contour) of the patient body part (col. 10, lines 59-62)
- d. assigning a location and shape of the patient body part in the navigation system via a position of the at least one marker captured by the camera (col. 5, lines 44-45, col. 10, lines 46-67, and figure 5)
- e. processing the shape of the patient body part by the navigation system monitoring a treatment zone to incorporate the outer shape of the patient body part in navigation (col. 10, lines 59-67 and figure 5).

Cosman fails to explicitly disclose that the three dimensional shape (contour) of the patient body is established by mapping an outline of the patient body part in multiple focusing distances of the camera.

Nayar discloses a method of detecting the shape of an object, the method comprising:

- i. producing a camera image of the object (page 221, section 6 and figure 9a)
- ii. mapping an outline of the object, the outline appearing sharp in the image, in a first plane by means of an analyzer connected to the camera (page 218, section 1.3 and page 222). Nayar explains that focus measures F(x, y, d) are determined for each focal plane di (i=1...M). Nayar further explains that the focal plane (di) where the focus measure becomes maximum (d) is obtained with respect to all coordinate points (x, y), and are used to determine the points on the object surface, thereby resulting in an image of the solid shape object (page 222, section 8 and figure 9b). Note that d(x,y) represents the z-coordinate value (depth) of the focal plane that includes a point on the object surface at (x, y). Therefore, all the points on the

object surface are determined for each focal plane (di, i=1, 2, ...M). The Examiner notes that determining all the points of the object surface for each focal plane (the points on the object surface having the same d values) is analogous to mapping an outline of the object in each focal plane, since the surface points in each focal plane represent a cross section of the object surface at a particular height (z=d), wherein the cross section is characterized by a plane that includes all the points of the object surface intersecting that plane, thereby forming an outline of the object surface (see figure 9b).

Nayar further discloses:

- iii. altering the focus distance of the camera (page 220, section 4 and page 221, section 6)
- iv. mapping a sharp outline of the object in a second plane by means of an analyzer [page 222, section 8. See also the discussion in regards to (ii) above]
- v. repeating steps ii) to iv) until a sufficient number of outlines has been mapped so that the three-dimensional shape of the object can be established (page 222 and figure 9b).

Cosman and Nayar are both concerned with image processing systems for detecting the three dimensional shape of an object. Nayar provides a fast, efficient, and reliable shape extraction method that is capable of detecting the three-dimensional shape of an object having a variety of different surfaces at a higher speed (Nayar, page 218 and 223). Therefore, it would have been obvious to modify the method of Cosman, so that the three-dimensional shape of the patient body part is determined by mapping an outline of the patient body part in multiple focusing distances of the camera, as taught by Nayar, in order to reduce processing time and thereby enhance the treatment process.

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Referring to claim 2, Nayar further discloses that the differences in contrast are mapped to establish which outline appears sharpened in the image (page 221, section 6).

Referring to claim 3, Cosman discloses that the camera is a video camera (col. 10, lines 59-60), but fails to explicitly disclose that the video camera has a very small depth of sharpness. However, cameras having a very small depth of sharpness were exceedingly well known in the art. For example, Nayar discloses a camera having a very small depth of sharpness (page 221, right column and figure 8. Note that the camera on the microscope will have a very small depth of sharpness). Therefore, it would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

Referring to claim 4, Cosman further discloses that the markers are applied to the object to highlight specific points on the patient body part for identification (col. 5, lines 44-45 and col. 10, lines 64-67).

Referring to claim 5, Nayar further discloses that the analyzer used is a computer including an image processing program, in which digital signals are processed (page 223, section 9).

Referring to claim 6, Cosman further discloses that the camera can be used with a surgical microscope (col. 2, lines 13-20 and figure 4) but fails to explicitly disclose that the camera is used on a surgical microscope. Nayar discloses that the camera is used on a microscope (figure 8). Therefore, it would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

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Referring to claim 9, see the rejection of at least claim 1 above. Note that the "at least one marker" noted above, is interpreted as being analogous to "at least one fixed point" on the patient body part.

Referring to claim 10, Cosman further discloses that the method is used together with a navigation system for location referencing in surgical operations (col. 2, lines 13-29).

Referring to claim 11, Cosman further discloses that the shape of the patient body part is assigned to a shape determined by a preoperative scan to permit location correction (col. 10, lines 46-67).

Referring to claim 12, Cosman fails to explicitly disclose that the mapped shape of the patient body part is used to automatically focus object planes defined by the user.

Nayar explains that the mapped three dimensional shape of the object is obtained from d(x,y) values, wherein d is the z-coordinate (depth) of the focal plane where the focus measure becomes maximum for all coordinate values (x, y), as noted above. Therefore, the d(x, y) values of the mapped shape of the object in a selected focal plane (di, i=1, 2...M) will represent the points on the object surface that are in focus.

Nayar fails to explicitly disclose that a user defines the plane. Official notice is taken that it was exceedingly well known for users to define a plane in an object image. Therefore, it would have been obvious for a user to define a plane in the object image of Nayar, in order to enhance the flexibility of the system by allowing the user to analyze specific portions of the object image for further processing. Therefore, if the user defines a plane, the mapped shape of the object [d(x, y)] can be used to automatically focus the selected plane. It would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

Referring to claim 13, Cosman fails to explicitly disclose that the mapped shape of the patient body part is used to produce an image which is sharp at any depth.

Nayar discloses that the shape of the object is used to produce an image which is sharp at any depth [page 222. Nayar explains that the d(x, y) values are used to display an image of the solid shape object (figure 9b). The Examiner notes that the solid shape image obtained from the d(x, y) values is sharp at any depth, since d is the z-coordinate (depth) where the focus measure becomes maximum for all coordinate values (x, y). It would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Kim whose telephone number is 703-306-4038. The examiner can normally be reached on Mon thru Thurs 8:30am to 6pm and alternating Fri 9:30am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0377.

January 12, 2004

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2600